PENNSYLVANIA DEPARTMENT OF HEALTH
2020 – PAHAN – 531-10-08-ADV

ADVISORY: Guidance for Reporting Point of Care SARS-CoV-2 Test Results

DATE:	10/8/2020
TO:	Health Alert Network
FROM:	Rachel Levine, MD, Secretary of Health
SUBJECT:	**ADVISORY: Guidance on Reporting Point of Care SARS-CoV-2 Test Results**
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This transmission is a "Health Advisory" provides important information for a specific incident or situation; may not require immediate action.

HOSPITALS: PLEASE SHARE WITH ALL MEDICAL, PEDIATRIC, NURSING AND LABORATORY STAFF IN YOUR HOSPITAL**; EMS COUNCILS:** PLEASE DISTRIBUTE AS APPROPRIATE; **FQHCs:** PLEASE DISTRIBUTE AS APPROPRIATE **LOCAL HEALTH JURISDICTIONS**: PLEASE DISTRIBUTE AS APPROPRIATE; **PROFESSIONAL ORGANIZATIONS:** PLEASE DISTRIBUTE TO YOUR MEMBERSHIP; **LONG-TERM CARE FACILITIES:** PLEASE SHARE WITH ALL MEDICAL, INFECTION CONTROL, AND NURSING STAFF IN YOUR FACILITY

- The U.S. Food and Drug Administration (FDA) has issued Emergency Use Authorizations (EUA) for a number of COVID-19 point of care (POC) tests for rapid detection of SARS-CoV-2.
- These POC tests may be used by both traditional healthcare providers (e.g., hospitals, outpatient providers) and by non-traditional settings who have appropriate CLIA Certificate to conduct this testing.
- All entities conducting these POC tests are required to report these results, including positive, negative, and inconclusive/indeterminate, to public health authorities through PA-NEDSS.
- A number of mechanisms have been established to ensure reporters can be compliant in providing the results of POC tests. Information regarding these reporting mechanisms are detailed in the message below.

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA) CERTIFICATE

Any entity utilizing Point-of-Care (POC) tests for COVID-19 must have a Pennsylvania laboratory permit and a Clinical Laboratory Improvement Amendments (CLIA) Certificate. If you already have a Pennsylvania laboratory permit and CLIA Certificate, you must also ensure that COVID-19 is listed in your test menu. Please see Understanding Clinical Laboratory Regulation in Pennsylvania for more information. If you have questions about laboratory permits or CLIA certification, please notify RA-DHPACLIA@pa.gov to assure laboratory compliance.

REPORTING

All entities conducting testing to identify SARS-CoV-2, the virus that causes COVID-19, are required to report positive, inconclusive/indeterminate, and negative results to PA-NEDSS within 24 hours of test completion. PA-NEDSS is a secure, web-based system used in Pennsylvania for disease reporting and surveillance. There are a number of mechanisms that have been established to ensure reporters can be compliant in providing the results of POC tests. These mechanisms are outlined below.

All reporters must request a PA-NEDSS account if they do not already have one. This can be done by completing a Prime Contact Information Form and sending this form to PA-NEDSS@pa.gov. Once access has been established with PA-NEDSS, a facility can opt to report in one of the following ways.

- Individual patient test results can be entered manually into PA-NEDSS. Instructions for reporting point of care test results and an accompanying FAQ to assist reporters with this entry can be found at the following:
  - PA-NEDSS Manual Test Reporting Instructions for Point of Care (POC) Tests
  - Reporting FAQs
- Reporters who would prefer to record results in an Excel file and upload results all at one time can request reporting via this option. Any PA-NEDSS user can request access to this template by sending an email to RA-DHNEDSS@pa.gov. It should be noted that this process can take time to set up and perform data quality checks to ensure data accuracy and so reporters should be prepared to manually report data until this mechanism is fully established.

If an individual is tested on multiple platforms (e.g., antigen and PCR), results from both platforms must be recorded in PA-NEDSS regardless of result. For example, if a positive antigen test is followed by a negative PCR, both results must be recorded in PA-NEDSS.

Additional information about the use of antigen test and factors that should be considered in the interpretation of their results can be found in HAN-532.

If you have questions about this guidance, please call your local health department or **1-877-PA-HEALTH** (**1-877-724-3258**).

Categories of Health Alert messages:
Health Alert: conveys the highest level of importance; warrants immediate action or attention.
Health Advisory: provides important information for a specific incident or situation; may not require immediate action.
Health Update: provides updated information regarding an incident or situation; unlikely to require immediate action.

This information is current as of October 8, 2020 but may be modified in the future. We will continue to post updated information regarding the most common questions about this subject.